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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,964	02/12/1999	KAI W. WUCHERPFENNIG	HUIP-P01-005	9407

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/248,964	WUCHERPFENNIG ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,103 and 114-147* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *103 and 114-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/075,351 and is a continuation of PCT/US97/14503, which claims the benefit of the filing date of provisional application 60/024,007.

Claims 21-102 and 104-113 have been canceled previously.

Claims **1-20 stand as withdrawn**.

Claims **103 and 114-147 are currently pending and are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 103 and 114-147 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

It was previously stated: "The claims are broadly drawn to recombinant MHC class II complexes comprising a first polypeptide having the extracellular domain of an MHC class II alpha chain joined to a first "coiled-coil dimerization domain" and a second polypeptide having the extracellular domain of an MHC class II beta chain joined to a second "coiled-coil dimerization domain."

The term "dimerization domain" is defined in the specification at page 3, lines 24-28 for example, as:

> "It has been suggested that "dimerization domains" of known, stable dimeric proteins may be genetically engineered into fusion proteins to promote the formation of stable dimeric fusion proteins. For example, synthetic peptides of the isolated Fos and Jun leucine zipper dimerization domains with added N--terminal cysteine residues and (Gly)2 linkers, were shown to assemble as soluble heterodimers with interchain disulfide bridges..."

Page 5, lines 13-16 for example, defines "coiled-coil dimerization domains" thusly:

> "In some preferred embodiments, the dimerization domains of the Class 11 MFIC binding domain fusion proteins comprise coiled-coil dimerization domains, such as leucine zipper domains. Preferably, the leucine zipper domains include at least four leucine heptads. In one preferred embodiment, the leucine zipper domain is a Fos or Jun leucine zipper domain."

At pages 33-34, the specification defines "coiled-coil dimerization domains" as being exemplified by leucine zippers from naturally occurring sources, such as Fos or Jun, or as artificial or synthetic leucine zippers.

However, the instant specification does not disclose any other type of "coiled-coil dimerization domain." Accordingly, the written description in the instant specification only sets forth leucine zipper dimerization domains as being the only type of "coiled-coil dimerization domain" that the artisan would be able to recognize as being in Applicant's possession at the time of the invention.

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement

> The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001 see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 1 9 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 1 12 is severable from its enablement provision (see Vas-Cath at page 1115).

With the exception of natural or artificial leucine zipper dimerization domains, the skilled artisan cannot envision the detailed structure of the encompassed coiled-coil dimerization domains and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016).

Claims 122-124 and 142-144 are included because the claims require only one of the dimerization domains to be a leucine zipper domain, without specifying the nature of the second coiled-coil dimerization domain."

Applicant's arguments filed September 6, 2005 have been fully considered but they are not persuasive.

Applicant traverses the ground of rejection on the grounds that, first, the instant specification does not only teach leucine zippers as a coiled-coil domain and, second, because the artisan would be able to envisage other coiled-coil dimerization domains that would be usable in the presently claimed invention.

In regard to the first ground of traversal, Applicant asserts that the specification also teaches at page 33, lines 21-24 that the transmembrane regions of HLA-DR α and β chains also assemble into coiled-coil structures. It is noted, however, that the specification teaches that these transmembrane

regions "are thought to" assemble into coiled-coil structures and that they do so within the "hydrophobic environment of the cell membrane." In contrast, the instantly claimed invention requires that the dimerization domains "associate in solution at physiological conditions." Accordingly, the transmembrane regions of the MHC heterodimer as taught in the specification do not provide an example of a coiled-coil dimerization domain that satisfies the metes and bounds of the claimed invention.

In regard to the second ground of traversal, applicant is reminded that obviousness of other coiled-coil dimerization domains to the artisan is not the standard for the inclusion of embodiments that are not described in the specification or claims as originally filed. Entitlement to a filing date does not extend to subject matter that is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). The fact remains that the only coiled-coil dimerization domains satisfying the metes and bounds of the claimed invention that are described in the instant specification is natural or artificial leucine zipper dimerization domains.

Conclusion

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. FV
Patent Examiner
November 22, 2005

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644